REMARKS

Rejection of Claims 53-57, 62 and 63 under 35 U.S.C. §112, First Paragraph

Claims 53-57, 62 and 63 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.

The Examiner objects to the phrase "said pharmaceutical composition does not contain progesterone". This phrase has now removed from claim 53 and the word comprising has been exchanged with the phrase "consisting essentially of." Applicant finds that claim 53 accordingly fulfills the written description requirements. Applicant also respectfully directs the Examiner's attention to the argumentation presented in the latest filed response regarding non-obviousness of the present invention and incorporates those remarks herein by reference.

Claims 62-63 are hereby canceled such that the rejection is submitted to be moot with respect to these claims.

In view of the above-mentioned amendment Applicant submits that claims 53-57 comply with the written description requirement and it is therefore respectfully requested that the rejection be withdrawn.

Rejection of Claims 30-35, 38-57 and 59-63 under 35 U.S.C. §103(a)

Claims 30-35, 38-57 and 59-63 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Zeng, U.S. Patent No. 6,440,949.

Examiner argues that claims 30-35, 38-57 and 59-63 are obvious in view of Zeng (US 6,440,949). Zeng describes the use of solutions containing 2.5 to 17% of saccharide for treatment of bacterial vaginosis.

The Examiner argues that it would be obvious for one having ordinary skill in the art to modify the composition disclosed in Zeng to such an extent that the composition would contain a significantly higher concentration of saccharide than described in Zeng. We respectfully disagree.

The present application relates to a composition having a high concentration of saccharide. It is clear from the application that the effectiveness of said composition is related to the amount of saccharide compared to the amount of total solids. In tablets, and the like, dry matter constitutes 100%

of the compositions, and the present application provides solid compositions comprising at least 75% of saccharide. Compositions formulated as solutions and suspensions may have a high concentration of saccharide compared to amount of total solids even if the percentage of saccharide is lower and the present application provides suspensions or gels comprising at least 40% of saccharide.

These saccharide contents are very far from the range of 2.5% to 17% taught by Zeng. The teaching of Zeng does not motivate the skilled person to increase the saccharide content.

Firstly, Zeng teaches the use of low-saccharide solutions. Saccharides such as lactose are not soluble at high concentration, and thus the skilled person would be discouraged from using a high saccharide content.

Second, the data presented in Zeng includes the effect of different compositions containing different saccharides on Gram-positive Bacilli growth and pH (example 2-4, table 2-4). Three different concentrations of saccharide in the compositions are tested. One symptom of bacterial vaginosis is a higher pH than normal in the vaginal secretions.

As it is evident from the data presented in the tables of Zeng it is not all of the proposed saccharides which result in a reduced pH.

The composition with the overall best effect on lowering of pH is the composition of example 2 (8 of the tested compositions demonstrate a lowered pH after 24 hour culture). This composition comprises either 5% (W/V) of a monosaccharide or 10% (W/V) of a disaccharide.

If the data is viewed in more detail for the monosaccharide glucose it demonstrates that the best concentration of this saccharide with respect to lowering of pH is a concentration of 2.5% (W/V). The data for the disaccharide lactose demonstrates that the best concentration of this saccharide with respect to lowering of pH is a concentration of 10% (W/V). The highest concentration of saccharide tested in Zeng is 17% of the disaccharides. Lactose demonstrates no lowering of pH at this concentration (see Table 4).

Accordingly the skilled person would have no reasonable expectation that e.g. a solid formulation or a suspension or gel of undissolved saccharides would be effective.

Based on Zeng the skilled person would have no incitement to change the composition by increasing the saccharide content as this would, in view of Zeng and common general knowledge, be considered a disadvantage.

The composition of Zeng is based on a water solution and the use of xantham gum to create a gel is mentioned (col. 5, l. 53-56). Further disclosed is the administration of the liquid composition by use of a tampon (col. 7, l. 41-43). Nowhere in Zeng is it mentioned or even suggested to use other administration forms. The composition of the present patent application makes it unnecessary to use either gelling agents or tampons for administration.

Based on the arguments presented above, the invention as claimed in claims 30-35, 38-57 and 59-63 are non-obvious in view of Zeng. Applicant therefore respectfully requests withdrawal of the rejection, reconsideration and allowance of the claims.

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Respectfully submitted,

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